

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ROY WILMOTH, JR.,
6160 Ivy Trails Drive
Olive Branch, MS 38654,

EDWIN R. BANKS,
128 Hunington Chase Drive
Madison, AL 35758,

MAUREEN PIEKANSKI,
430 Sanderson Street
Throop, PA 18512,

Plaintiffs,

v.

ALEX AZAR, in his capacity as Secretary of
the United States Department of Health and
Human Services,
200 Independence Avenue, S.W.
Washington, DC 20201,

Defendant.

Case No. _____

JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs Roy Wilmoth, Jr., Edwin R. Banks, and Maureen Piekanski (collectively, “Plaintiffs”) bring this action against Defendant Alex Azar, in his official capacity as Secretary of the United States Department of Health and Human Services (hereinafter, “the Secretary”), to obtain injunctive relief for violation of federal law. Plaintiffs make the following allegations based on the investigation of counsel, information and belief, and on personal knowledge.

I. SUMMARY

1. This case presents a simple question: is the Secretary bound by the Supreme Court’s decision in *Astoria Federal Savings & Loan v. Solimino*, 501 U.S. 104 (1991) such that collateral

estoppel can apply against the Secretary where the Secretary has previously litigated, and lost, an issue against the same party?

2. Likewise, having previously determined multiple times that coverage of a medical device to treat Plaintiffs' extremely lethal form of brain cancer was appropriate, is it arbitrary and capricious for the Secretary to decide otherwise when the facts and/or circumstances have not changed?

3. In the cases at issue here, the Secretary asserts that his regulations (rather than the directives of the Supreme Court) preclude collateral estoppel and that month-to-month differing decisions (where the facts and/or circumstances have not changed) on Plaintiffs' life-saving care are not arbitrary and capricious. Plaintiffs assert that those positions are wholly without merit.

4. Tragically, each of the Plaintiffs is suffering from a particularly deadly form of brain cancer (GBM)¹ and they are seeking coverage for life-saving treatment. In a particularly cruel twist, on a month-to-month basis, the Secretary is forcing the Plaintiffs to repeatedly prove that they are entitled to the treatment and the Secretary's decisions differ with no predictable pattern. Thus, the Secretary is playing a game of chance with the Plaintiffs' lives – maybe this month they will get life-saving treatment – maybe they won't.

II. JURISDICTION

5. This Court has jurisdiction over this action pursuant to 42 U.S.C. §§ 405(g) and 1395ff. All three Plaintiffs are filing suit after final decisions of the Medicare Appeals Council (acting on behalf of the Secretary) denying coverage of their Medicare claims (and, therefore, have exhausted their administrative remedies), the amount-in-controversy is more than \$1,630 (42

¹ Former Senators Edward Kennedy and John McCain also suffered, and died from, this kind of cancer.

U.S.C. §§ 1395ff(b)(1)(E)(i) and 1395ff(b)(1)(E)(iii)), and this suit was filed within 60 days of the Secretary's final decisions.

6. Venue is proper in this district pursuant to 42 U.S.C. § 1395ff(b)(2)(C)(iii) because this action is being brought in the District of Columbia.

III. PARTIES

7. Plaintiff Roy Wilmoth Jr. is an individual and a resident of the State of Mississippi. Mr. Wilmoth is eligible for Medicare on the basis of age (or disability) as previously determined by the Secretary.

8. Plaintiff Edwin R. Banks is an individual and a resident of the State of Alabama. Mr. Banks is eligible for Medicare on the basis of age (or disability) as previously determined by the Secretary.

9. Plaintiff Maureen Piekanski is an individual and a resident of the State of Pennsylvania. Mrs. Piekanski is eligible for Medicare on the basis of age (or disability) as previously determined by the Secretary.

10. Defendant Alex Azar is sued in his official capacity as the Secretary of Health and Human Services.

IV. LEGAL BACKGROUND

11. In *Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991), the Supreme Court held that:

We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in

adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

12. The application of collateral estoppel to agency determinations (even against agencies) has been affirmed in numerous cases. *See, e.g., Brewster v. Barnhart*, 145 Fed.App'x. 542 (6th Cir. 2005) (SSA ALJ bound by prior work determination).

V. FACTUAL BACKGROUND

Tumor Treatment Field Therapy (TTFT)

13. Glioblastoma multiforme (GBM) is an unusually deadly type of brain cancer. Without treatment, survival is typically 3 months. Even with traditional forms of treatment, the survival rate at 2 years after treatment is ~31%, while at five years, only ~5% of patients are living.

14. More recently, treating GBM using alternating electric fields has been developed. This is known as tumor treatment field therapy (TTFT). Alternating electric fields interfere with tumor cell replication and have been shown to dramatically increase the period during which the GBM does not progress, as well as overall survival rates. Indeed, TTFT has proven so effective that, in late 2014, a randomized clinical trial of TTFT was suspended because it would have been unethical to withhold TTFT treatment from the control group.²

² In much scientific research, study participants are randomly assigned to “control” and “test” groups. The “control” group does not receive the treatment being tested. In contrast, the “test” group does. Proceeding in this way facilitates the determination of which effects, if any, are the result of the tested treatment as opposed to normal variation among the study participants. During the course of a study, interim results are frequently measured to determine whether the study is proceeding as planned and whether any changes are needed. When the interim results indicate that the tested treatment has a significant effect on health or safety, either negative or positive, ethical guidelines dictate that the study should be halted. Thus, if the interim results indicate that the tested treatment was significantly more likely to result in death than the control

15. In ground-breaking papers published in the Journal of the American Medical Association (JAMA)³ in 2015 and 2017, TTFT was shown to increase the 2-year survival rate by more than 38% and to nearly triple the five-year survival rate.⁴

16. As reported, TTFT was the first significant advance in treating GBM in more than a decade. TTFT has become the standard of care for treating GBM and essentially all private insurers cover TTFT. TTFT saves and/or extends GBM patients' lives, in some instances, by years. Between January 2016 and December 2018, at least 93 scientific papers were published demonstrating the effectiveness of TTFT. It is given a level one recommendation in the National Comprehensive Cancer Network (NCCN) guidelines, *i.e.*, there is consensus, among the experts, based on a high level of evidence, that TTFT is a recommended intervention.

17. The sole supplier of the equipment that delivers TTFT is Novocure, Inc. which manufactures the Optune system. The Optune system is rented on a monthly basis. Thus, after a patient is prescribed the Optune system, they will have monthly claims for Medicare coverage. Sadly, there is no known cure for GBM and patients prescribed TTFT treatment will have to continue that treatment for the rest of their hopefully extended lives.

group, the study would be halted and the treatment no longer given to the "test" group. Likewise, if the interim result indicated that the tested treatment was literally life-saving, the study would be halted and the treatment would be made available to the "control" group. In those circumstances, withholding the treatment from the "control" group would be unethical.

³ The Journal of the American Medical Association (JAMA) is widely regarded as one of the most prestigious medical journal in the United States and the world.

⁴ See Stupp, et al., "MAINTENANCE THERAPY WITH TUMOR-TREATING FIELDS PLUS TEMOZOLOLIMIDE VS. TEMOZOLOLIMIDE ALONE FOR GLIOBLASTOMA: A RANDOMIZED CLINICAL TRIAL", JAMA, Vol. 314, No. 23, pgs. 2535-43 (December 15, 2015); Stupp, et al., "EFFECT OF TUMOR TREATING FIELDS PLUS MAINTENANCE TEMOZOLOLIMIDE VS. MAINTENANCE TEMOZOLOLIMIDE ALONE ON SURVIVAL IN PATIENTS WITH GLIOBLASTOMA", JAMA, Vol. 318, No. 23, pgs. 2306-2316 (December 19, 2017).

The Medicare Appeals Process

18. Claims submitted by beneficiaries enrolled in Original Medicare are subject to a five (5) level appeal process, that can (and typically does) take more than a year. At the first stage, a beneficiary submits a claim. If the claim is denied, the beneficiary can request “redetermination.” If the claim is still denied, the beneficiary can request “reconsideration.” If the claim is still denied, the beneficiary can appeal to an ALJ. If the ALJ denies the claim, the beneficiary can appeal to the Medicare Appeals Council. Finally, if the claim is still denied, the beneficiary can file suit in district court.

19. While the statutes and regulations require both ALJs and the MAC to issue decisions within 90 days, those deadlines are routinely missed. Thus, beneficiaries seeking coverage are often thrown into a multi-year effort to obtain final decisions in their cases before they can seek relief in a federal court.

a. Facts Specific to Mr. Wilmoth

20. Mr. Wilmoth is a 71-year-old retired telephone company employee, father of two (2) and grandfather to five (5). Along with his wife of nearly forty (40) years (Paulette), Mr. Wilmoth lives in Mississippi - just outside of Memphis, Tennessee. In his free time, Mr. Wilmoth enjoys restoring old cars and fishing.

21. Mr. Wilmoth was diagnosed with GBM in February 2016 and, after surgery and chemo-radiation, Mr. Wilmoth began using the Optune system in May 2017.

Favorable Decisions That Have Become Final

22. On December 13, 2018, ALJ Lissette Figueroa issued a decision in Appeal No. 1-7835293187 on TTFT claims related to the months of October, November, and December 2017

finding that Medicare coverage was appropriate for Mr. Wilmoth because it was “medically reasonable and necessary.”

23. The Secretary did not appeal Judge Figueroa’s decision and the decision became final on February 13, 2019.

24. On July 2, 2019, ALJ Joseph Petrylak issued a decision in Appeal No. 1-8415320334 on claims related to the months of July, August, and September 2018 finding that coverage was appropriate for Mr. Wilmoth because it was “medically reasonable and necessary.”

25. The Secretary did not appeal Judge Petrylak’s decision and the decision became final on September 2, 2019.

26. On April 25, 2019, ALJ Andrew Henningfeld issued a decision in Appeal No. 1-8236683474 on claims related to the months of January, February, and March 2018 finding that coverage was appropriate for Mr. Wilmoth because it was “medically reasonable and necessary.”

27. The Secretary did not appeal Judge Henningfeld’s decision and the decision became final on June 25, 2019.

The Decision At Issue In This Case

28. On May 7, 2019, ALJ Kenneth Bryant issued a decision in Appeal No. 1-8363484331 on claims related to the months of April, May, and June 2018. Contrary to the decision, *e.g.*, of ALJ Figueroa (which he had before him), ALJ Bryant held that TTFT treatment for Mr. Wilmoth “was not medically reasonable and necessary” and, therefore, was not a covered benefit.

29. Mr. Wilmoth timely appealed. In particular, Mr. Wilmoth noted the prior decisions from ALJs Figueroa, Petrylak, and Henningfeld finding Medicare coverage

appropriate. As a result, Mr. Wilmoth argued that the Secretary was collaterally estopped from re-litigating that issue.

30. In a decision issued on October 15, 2019, the Council held that, because its regulations (42 C.F.R. § 405.1108(a)) indicate that Council review is *de novo*, collateral estoppel does not apply. Thus, the Council denied Mr. Wilmoth's claim for coverage.

b. Facts Specific to Mr. Banks

31. Mr. Banks is a 74 year-old, software designer, father of three (3) and grandfather to five (5). Mr. Banks has a PhD in Mechanical Engineering from MIT and was employed in the aerospace business working on projects for NASA. Along with his wife of more than fifty (50) years (Betty), Mr. Banks currently lives in Madison, Alabama – just outside of Huntsville. In his free time, Mr. Banks performs missionary work (including translating the Bible into indigenous languages).

32. Mr. Banks was diagnosed with GBM in 2009 and, after surgery and chemo-radiation, Mr. Banks began using the Optune device in December 2013.

Favorable Decisions That Have Become Final

Appeal No. 1-8498071113

Appeal No. 1-8428973391

Appeal No. 1-8501252025

33. On June 6, 2019, ALJ Jeffrey Gulin issued decisions in Appeal Nos. 1-8498071113, 1-8428973391, and Appeal No. 1-8501252025 on claims related to the months of February and May-December 2018 finding that coverage was appropriate for Mr. Banks. Among other findings, Judge Gulin found that TTFT treatment was medically reasonable and necessary for Mr. Banks and a covered Medicare benefit. Thus, Judge Gulin ordered coverage of Mr. Bank's claims. Of note, the Secretary chose not to participate in the hearing conducted by Judge Gulin or to submit briefs.

34. The Secretary did not appeal Judge Gulin's decision and the decision became final on August 6, 2019.

The Decision At Issue In This Case

35. On June 3, 2019, ALJ Bruce Kelton issued a decision in Appeal No. 1-813649506 on claims related to the months of January, March and April of 2018. Contrary to the decisions by Judge Gulin, Judge Kelton held that TTFT was not medically reasonable and necessary for Mr. Banks and was not a covered benefit.

36. Mr. Banks timely appealed. In particular, Mr. Banks noted the prior decisions from ALJ Gulin finding coverage appropriate. As a result, Mr. Banks argued that the Secretary was collaterally estopped from re-litigating that issue.

37. When the Secretary did not issue a decision within the 90-day time frame provided by 42 U.S.C. § 1395ff(d)(2)(A), pursuant to 42 C.F.R. § 405.1132, Mr. Banks filed a notice of escalation on November 15, 2019 again arguing that the Secretary was collaterally estopped from denying coverage. When no response was received within the 5-day time limit of 42 C.F.R. § 405.1132(a)(1), ALJ Kelton's decision became the final decision of the Secretary and Mr. Banks timely filed this suit.

c. Facts Specific to Mrs. Piekanski

38. Mrs. Piekanski is a 64 year-old retired grocery store worker, mother/step-mother of four (4), and grandmother to ten (10). Along with her husband of more than 20 years (Theodore), Mrs. Piekanski currently lives in Throop, Pennsylvania – just outside Scranton. In her free time, Mrs. Piekanski enjoys music and spending time with her family.

39. Mrs. Piekanski was diagnosed with GBM in 2011 and, after surgery and chemo-radiation, Mrs. Piekanski began using the Optune device in August 2011.

Favorable Decisions That Have Become Final

Appeal No. 1-7835229465

40. On November 7, 2018, ALJ Jeffrey Gulin issued a decision on claims related to the months of September, October, and November 2018 finding that coverage was appropriate for Mrs. Piekanski. Among other findings, Judge Gulin found that TTFT treatment was safe and effective and medically reasonable and necessary for Mrs. Piekanski. Thus, Judge Gulin ordered coverage of Mrs. Piekanski's claims. Of note, the Secretary chose not to participate in the hearing conducted by Judge Gulin or to submit briefs.

41. The Secretary did not appeal Judge Gulin's decision and the decision became final on January 7, 2019.

Appeal No. 1-8637781229

42. On September 13, 2019, ALJ Ryan Glaze issued a decision on claims related to the months of June, July, and August 2018 finding that coverage was appropriate for Mrs. Piekanski. Among other findings, Judge Glaze found: 1) that Mrs. Piekanski's GBM was "newly diagnosed" (as opposed to "recurrent"); and 2) that TTFT treatment was safe and effective and medically reasonable and necessary for Mrs. Piekanski. Thus, Judge Glaze ordered coverage of Mrs. Piekanski's claims. Of note, the Secretary chose not to participate in the hearing conducted by Judge Glaze or to submit briefs.

43. The Secretary did not appeal Judge Glaze's decision and the decision became final on November 13, 2019.

Appeal No. 1-8415573880

44. On June 4, 2019, ALJ Jenifer Soulikias issued a decision on claims related to the months of September, October, and November 2018 finding that coverage was appropriate for

Mrs. Piekanski. Among other findings, Judge Soulikias found that TTFT treatment was safe and effective and medically reasonable and necessary for Mrs. Piekanski. Thus, Judge Soulikias ordered coverage of Mrs. Piekanski's claims. Of note, the Secretary chose not to participate in the hearing conducted by Judge Soulikias or to submit briefs.

45. The Secretary did not appeal Judge Soulikias' decision and the decision became final on August 4, 2019.

The Decision At Issue In This Case

46. On January 18, 2019, ALJ Glaze issued a decision in Appeal No. 1-8071086400 related to claims for coverage for the months of December 2017 through February 2018. There, contrary to the decisions issued above, Judge Glaze held that Mrs. Piekanski was not entitled to coverage. For example, contrary the decision issued in September 2019, e.g., Judge Glaze held that Mrs. Piekanski's GBM was considered "recurrent" rather than "newly diagnosed." Again, contrary to the decisions listed above, Judge Glaze held that TTFT was not medically reasonable and necessary for Ms. Piekanski.

47. Mrs. Piekanski timely appealed. In particular, Mrs. Piekanski noted the prior decisions from ALJs Gulin, Glaze, and Soulikias finding coverage appropriate. As a result, Mrs. Piekanski argued that the Secretary was collaterally estopped from re-litigating that issue.

48. When the Secretary did not issue a decision with the 90-day time frame provided by 42 U.S.C. § 1395ff(d)(2)(A), pursuant to 42 C.F.R. § 405.1132, Mrs. Piekanski filed a notice of escalation on November 15, 2019 again arguing that the Secretary was collaterally estopped from denying coverage. When no response was received within the 5-day time limit of 42 C.F.R. § 405.1132(a)(1), ALJ Glaze' decision became the final decision of the Secretary and Mrs. Piekanski timely filed this suit.

CAUSES OF ACTION

COUNT I

Violation of 42 U.S.C. §405(g)
(contrary to law)

49. Plaintiffs hereby incorporates paragraphs 1-48 herein.

50. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as contrary to law, as arbitrary and capricious, an abuse of discretion, and unsupported by the evidence, and issue an order finding that Plaintiffs' claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT II

Violation of 5 U.S.C. § 706(1)
(unlawfully withheld or unreasonably delayed)

51. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as unlawfully withheld or unreasonably delayed and unsupported by the evidence, and issue an order finding that Plaintiffs' claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT III

Violation of 5 U.S.C § 706(2)(A)
(arbitrary and capricious, abuse of discretion, not in accordance with law)

52. Paragraphs 1-51 are incorporated by reference as if fully set forth herein.

53. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law, and issue an order finding that Plaintiffs' claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT IV
Violation of 5 U.S.C § 706(2)(C)
(in excess of statutory jurisdiction, authority, or
limitations or short of statutory right)

54. Paragraphs 1-53 are incorporated by reference as if fully set forth herein.

55. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as in excess of the Secretary's authority and limitations and short of Plaintiffs' statutory rights and issue an order finding that Plaintiffs' claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT V
Violation of 5 U.S.C § 706(2)(D)
(without observance of procedure required by law)

56. Paragraphs 1-55 are incorporated by reference as if fully set forth herein.

57. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as done without observance of the procedure required by law and issue an order finding that Plaintiffs' claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT VI
Violation of 5 U.S.C § 706(2)(E)
(not supported by substantial evidence)

58. Paragraphs 1-56 are incorporated by reference as if fully set forth herein.

59. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as not supported by substantial evidence and issue an order finding that Plaintiffs' claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court:

A. Enter an order:

- (1) finding that the Secretary is collaterally estopped from relitigating whether TTFT treatment for Plaintiffs is a covered benefit;
 - (2) finding that, in light of the prior decisions granting coverage, the denials at issue in this case are arbitrary and capricious;
 - (3) directing the Secretary to cover the claims at issue in this case;
- B. Award attorney's fees and costs to Plaintiffs as permitted by law; and
- C. Provide such further and other relief this Court deems appropriate.

Dated: November 26, 2019

Respectfully submitted,

/s/Daniel Z. Herbst
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